

The mission of the Office of Biotechnology Products is to protect the public health by assuring the quality, safety, efficacy, availability and security of recombinant therapeutic protein and monoclonal antibody products. The Office of Biotechnology Products has 2 divisions: the Division of Therapeutic Proteins (DTP) and the Division of Monoclonal Antibodies (DMA). The Office is also supported by a Biological Products Facility Staff in the CDER Office of Compliance.

The Division of Monoclonal Antibodies ensures that safe, efficacious and high quality monoclonal antibody products are available to the American people to diagnose, prevent and treat the illnesses that afflict them. Our activities include application review (Chemistry, Manufacturing and Controls: CMC), facility inspection – Prior Approval Inspections (PAI) and biannual Good Manufacturing Practices (GMP), research supporting biotechnology policy, policy and guidance document development, as well as training – internal and external